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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,913	12/17/2001	Peter Beyer		5922

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SYNGENTA BIOTECHNOLOGY, INC.  
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EXAMINER
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KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

MAIL DATE	DELIVERY MODE
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08/07/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

09/914,913

Applicant(s)

BEYER ET AL.

Examiner

Russell Kallis

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16,32-43 and 60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16,32-43 and 60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 8/15/2006 has been entered.

Rejection of Claims 16 and 32-43 under 35 U.S.C. 102(b) is withdrawn in view of Applicant's amendments and arguments.

Rejection of Claims 16 and 32-43 under 35 U.S.C. 103(a) is withdrawn in view of Applicant's amendments and arguments.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-15, 17-31 and 44-59 are cancelled. Claim 60 is newly filed. Claims 16, 32-43, and 60 are pending and examined.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16, 32-43 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burkhardt P. *et al.*, in RICE GENETICS III; Proceeding of the Third International Rice Genetics Symposium; International Rice Research Institute (IRRI), 1996; Khush G. S. ed., in view of Shewmaker C. in WO 99/07867 published 18 February 1999.

The claims are broadly drawn to a method of producing a plant cell that accumulates  $\beta$ -carotene in normally carotenoid free tissue by transformation with a plant phytoene synthase and a bacterial phytoene desaturase and plants transformed therewith.

Burkhardt teaches a method of transforming rice plants (*Liliopsida*) with DNA molecules capable of expressing in plant cells consisting of a phytoene synthase and phytoene desaturase from daffodil, using either the CaMV35S or the endosperm tissue specific rice *Gtl* promoter, and the *hpt* hygromycin antibiotic selection gene under control of a constitutive promoter and suggest a strategy for using single genes or combinations of genes from the carotenoid biosynthetic pathway (page 819, lines 27-44); that rice milled endosperm has virtually no beta-carotene (page 818, lines 9-11); the availability of genes encoding the four necessary enzymatic activities for beta-carotene biosynthesis in plants and bacteria (page 819, lines 16-22); and the accumulation of high levels of phytoene in the seeds of several lines of rice plants transformed with phytoene synthase and phytoene desaturase from daffodil (page 820, lines 1-2).

Burkhardt does not teach a bacterial phytoene desaturase encoding sequence fused to a sequence encoding the pea Rubisco small subunit transit peptide; a vector encoding system derived from *Agrobacterium tumefaciens*; or a plant transformed with a bacterial phytoene desaturase encoding sequence.

Shewmaker teaches transformation of *Brassica napus* plants with *crtB* and *crtI* from *E. uredovora* fused to the pea Rubisco small subunit transit peptide; wherein the transformed plants produced seeds that had several hundred fold increases of  $\beta$ -carotene (see Example 1 pages 26-27 in parts 1 and 2 for cloning and p.28-29 for transformation vectors; and Table 7 page 42 for  $\beta$ -carotene levels); and that genes for plant phytoene synthase and bacterial phytoene desaturases were known in the art (pages 9-10).

It would have been obvious at the time of invention to modify the invention of Burkhardt to include the polynucleotide encoding the *Erwinia uredova* bacterial phytoene desaturase and the vector encoding system derived from *A. tumefaciens* taught by Shewmaker. One of skill in the art would have been motivated by the teachings of Burkhardt that the genes encoding the enzymes required for beta-carotene biosynthesis from plants and bacteria were available in the art at the time of filing, as also taught by Shewmaker and Applicant's specification; and that rice endosperm contains GGPP the substrate for phytoene synthase as taught by Burkhardt, and is thus a valuable tool for engineering provitamin A production, and by the success of Burkhardt in transforming rice with phytoene synthase (daffodil) and phytoene desaturase (daffodil) and expressing the plant phytoene synthase (daffodil) in the endosperm of rice seeds resulting in high levels of phytoene, the substrate for phytoene synthase; and by the success of Shewmaker in producing several hundred fold increases of  $\beta$ -carotene in seeds of *Brassica napus* transformed with bacterial phytoene synthase (*crtB*) and bacterial phytoene desaturase (*crtI*) from *Erwinia uredova*; that one would have had a reasonable expectation of success in transforming a rice plant with a plant phytoene synthase and a bacterial phytoene desaturase; and in producing beta carotene in the endosperm of rice given the success of Shewmaker and Burkhardt.

In response to Applicant's remarks that D2 (i.e. Burkhardt *et al.*) does not teach or suggest a method for producing  $\beta$ -carotene in the endosperm of rice, Applicant's attention is directed to Applicant's remarks on page 9 of the response under 103, where Applicant states that "D2 (i.e. Burkhardt *et al.*) suggests that four enzymes are necessary for  $\beta$ -carotene biosynthesis in the rice endosperm"; and thus the reference does suggest a method for producing  $\beta$ -carotene in the endosperm of rice and does not teach away as stated by Applicant. In addition, the authors state that it is their strategy to transform with single heterologous carotenoid biosynthetic genes or several genes in combination from the carotenoid biosynthesis pathway on page 819 in lines 27-33 the 6<sup>th</sup> full paragraph.

All claims are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.  
July 30, 2007

RUSSELL P. KALLIS, PH.D.  
PRIMARY EXAMINER

*Russell Kallis*